

Appendix 3 - Amended Specification

The paragraph in the specification at page 11, lines 1-5, now reads as follows:

A7
In the present invention, the preferred hydralazine compound is hydralazine, which is preferably administered in the form of a pharmaceutically acceptable salt and most preferably in the form of hydralazine hydrochloride. Hydralazine hydrochloride is commercially available from, for example, Lederle Standard Products, Pearl River, NY; and Par Pharmaceuticals Inc., Spring Valley, NY.

[The paragraph in the specification at page 11, lines 10-12, now reads as follows:

A8
Isosorbide mononitrate is commercially available, for example, under the trade names IMDUR® (A. B. Astra, Sweden); MONOKET® (Schwarz Pharma, Milwaukee, WI); and ISMO® (Wyeth-Ayerst Company, Philadelphia, PA).

[The paragraph in the specification at page 14, lines 17 to 25, now reads as follows:

A9
While individual needs may vary, determination of optimal ranges for effective amounts of the compounds and/or compositions is within the skill of the art. Generally, the dosage required to provide an effective amount of the compounds and compositions, which can be adjusted by one of ordinary skill in the art, will vary depending on the age, health, physical condition, sex, diet and medical condition of the patient, the severity of the cardiovascular disease, the route of administration, pharmacological considerations such as the activity, efficacy, pharmacokinetic and toxicology profiles of the particular compound used, whether a drug delivery system is used, and whether the compound is administered as part of a drug combination.

The paragraph in the specification at page 23, lines 21 to 25, now reads as follows:

A¹⁰ Prior studies in hypertension have suggested that reduced responsiveness to ACE inhibitors may be attributed to a lower PRA in the black population. Indeed, the differential benefit in V-HeFT II of ACE inhibitor therapy in whites compared to blacks was particularly prominent in those with a prior history of hypertension in whom PRA was significantly lower in blacks than in whites.